DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2008

Marc J. Scheineson
Alston & Bird, LLP
950 F Street, NW
Washington, DC 20004

RE: 2007A-0332 (Advisory Opinion Request for Mandatory Black Box Warnings on All Bovine Thrombin Products)

Dear Mr. Scheineson:

In your letters to the Food and Drug Administration (FDA) dated August 24, 2007 and October 11, 2007, you requested, pursuant to FDA's regulations at 21 CFR 10.85, that FDA issue an Advisory Opinion with respect to our position on black box warnings for bovine thrombin-based hemostatic products. You highlighted your opinion that labeling inconsistencies raise both safety and marketplace issues.

Your request raises issues requiring review and consideration by Agency officials in various offices. Consequently, FDA has been unable to reach a decision at this time on these issues. We will advise you when we have reached a decision on your request.

If you have any questions, please contact Ruth Fischer of the Center for Devices and Radiological Health's Regulations Staff at (240)276-2350.

Sincerely yours,

Daniel G. Schultz, M.D.
Director
Center for Devices and
Radiological Health